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09/470494

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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BOSTON, MA 02110

EXAMINER

GAMBEL, P.

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

07/13/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 4/20/01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

shortened statutory period for response to this action is set to expire 1 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 136(a).

## Disposition of Claims

- Claim(s) 1-103 is/are pending in the application.  
Of the above, claim(s) is/are withdrawn from consideration.  
Claim(s) is/are allowed:  
Claim(s) is/are rejected.  
Claim(s) is/are objected to.  
Claim(s) 1-103 are subject to restriction or election requirement.

## Application Papers

- See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.  
The drawing(s) filed on is/are objected to by the Examiner.  
The proposed drawing correction, filed on is ☐ approved ☐ disapproved.  
The specification is objected to by the Examiner.  
The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.  
☐ received.  
☐ received in Application No. (Series Code/Serial Number)  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- Notice of Reference Cited, PTO-892  
Information Disclosure Statement(s), PTO-1449, Paper No(s).  
Interview Summary, PTO-413  
Notice of Draftperson's Patent Drawing Review, PTO-948  
Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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**DETAILED ACTION**

1. Applicant's submission, filed 4/3/0/01 (Paper No. 10), has placed this application in compliance with the Sequence Rules.

2. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods. The method rely upon anti-CD40L antibody/soluble CD40L and NF- $\kappa$ B inhibitor compounds which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species.

In addition, it is noted Group I comprises Claims 1- 40 and 47-66, drawn to methods of inducing TCR rearrangement, methods of promoting T cell maturation and methods of inducing T cell reactivity with a CD40 binding agent, because it appears that the preamble recites different mechanisms of action of essentially the same procedures. Applicant is invited to point out distinctions between these Groups, if there are any or that there are any intended distinctions between the recitation in these preambles.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1- 40 and 47-66, drawn to methods of inducing TCR rearrangement, methods of promoting T cell maturation and methods of inducing T cell reactivity with a CD40 binding agent, classified in Class 424, subclasses 130.1 and 184.1.

II. Claims 41-46, drawn to methods of inhibiting TCR rearrangement with an agent that inhibits CD40 induced T cell rearrangement (e.g. anti-CD40L antibody, soluble CD40L), classified in Class 424, subclass 130.1 and 184.1

III. Claims 41-46, drawn to methods of inhibiting TCR rearrangement with an agent that inhibits CD40 induced T cell rearrangement (NF- $\kappa$ B inhibitor), classified in Class 424, subclass 130.1 and 184.1

IV. Claims 47-84, drawn to methods of inhibiting environmental stress-induced cell-death of a T cell with a CD40 binding agent, classified in Class 424, subclass 130.1 and 184.1

V. Claims 85-103, drawn to methods of enhancing environment stress-induced T cell death by contacting T cell with a CD40-binding agent, classified in Class 424, subclass 130.1 and 184.1.

4. Inventions I/II/III/IV/V are different methods which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

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5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-V is not required for any other group from Groups I-V and Groups I-V have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed Group I/II/IV/V: wherein the CD40 binding agent is:

- A) CD40 ligand or
- B) anti-CD40 antibody.

These species are distinct because their structures and modes of action are different.

If Group I is elected, then in addition;, this application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the co-stimulatory agent is:

- A) a costimulatory molecule.
- B) a cytokine.

These species are distinct because their structures and modes of action are different.

If a costimulatory molecule is elected;

Then, in addition; this application contains claims directed to the following patentably distinct species of the claimed Group I-V: wherein the co-stimulatory molecule is:

- A) TSA-1,
- B) CD2
- C) CD5,
- D) CD24,
- E) CD28,
- F) CD49a,
- G) CD80,
- H) CD81 or
- I) CD86.

These species are distinct because their structures and modes of action are different.

If a cytokine is elected;

Then, in addition; this application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the cytokine is:

- A) IL-2 or
- B) IL-4.

These species are distinct because their structures and modes of action are different.

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Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 41, 47 and 85 are generic.

7. This application contains claims directed to the following patentably distinct species of the claimed Group III: wherein the NF- $\kappa$ B inhibitor (see page 18 of the specification) is:

- A) I $\kappa$ B $\alpha$  super-repressor,
- B) curcumin,
- C) phenylarsine oxide,
- D) SN-50,
- E) acrolein,
- F) ceramide, or
- G) flavonoids..

These species are distinct because their structures and modes of action are different

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 41 is generic.

8. If Groups IV or V are elected then in addition; this application contains claims directed to the following patentably distinct species of the claimed Groups IV/V: wherein the environmental stress is:

- A) chemical stress,
- B) oxidative stress,
- C) physical stress, or
- D)  $\gamma$  irradiation.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 47 and 85 are generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
July 2, 2001

PHILLIP GAMBEL